PCT

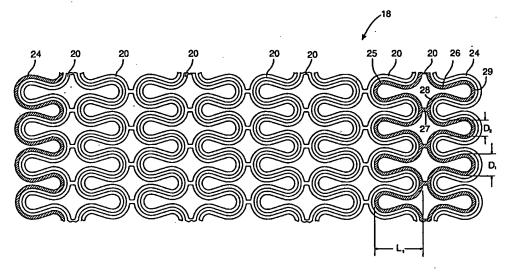
WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| 51) International Patent Classification 7: | | (11) International Publication Number: | WO 00/15151 |
|---|--------|--|----------------------------|
| A61F 2/06 | A1 | (43) International Publication Date: | 23 March 2000 (23.03.00) |
| 21) International Application Number: PCT/US 22) International Filing Date: 14 September 1999 | | CH, CY, DE, DK, ES, FI, FR, | |
| 30) Priority Data: 09/156,267 16 September 1998 (16.09.) 71) Applicant: ISOSTENT, INC. [US/US]; 1075 Oke Road, Belmont, CA 94002 (US). 72) Inventors: TURNLUND, Todd, H.; 811 Mulbe Sunnyvale, CA 94087 (US). DINH, Minh, Compton Court, Union City, CA 94568 (US). 74) Agent: BEYER, Steve, D.; Beyer & Weaver, LLP, 61059, Palo Alto, CA 94306 (US). | i Coun | e. 17 | ime limit for amending the |

(54) Title: LINKAGE STENT



(57) Abstract

A variety of stent designs that utilize interlocking rings are disclosed. Each ring is arranged to have a plurality of expandable loops. In some embodiments, some of the loops on each ring are arranged to interlock with a portion of an adjacent ring. The mating structure on the adjacent ring may take the form of loops or a dedicated interlocking structure. In other embodiments, separate interlocking members are used to interlock adjacent rings.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
|----|--------------------------|----|---------------------|------|-----------------------|------|--------------------------|
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland . |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ ` | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | | Republic of Macedonia | TR | Turkey |
| BG | Bulgaria | HU | Hungary | ML | Mali | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MN | Mongolia | UA | Ukraine |
| BR | Brazil | IL | Israel | MR | Mauritania | UG | Uganda |
| BY | Belarus | IS | Iceland | MW | Malawi | US | United States of America |
| CA | Canada | IT | Italy | MX | Mexico | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NE | Niger | VN | Vict Nam |
| CG | Congo | KE | Кепуа | . NL | Netherlands | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NO | Norway | zw | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's | NZ | New Zealand | | |
| CM | Cameroon | | Republic of Korea | PL | Poland | | |
| CN | China | KR | Republic of Korea | PT | Portugal , | | |
| CU | Cuba | KZ | Kazakstan | RO | Romania | | |
| CZ | Czech Republic | LC | Saint Lucia | RU | Russian Federation | | |
| DE | Germany | LI | Liechtenstein | SD | Sudan | | |
| DK | Denmark | LX | Sri Lanka | SE | Sweden | | |
| EE | Estonia | LR | Liberia | SG | Singapore | | |

LINKAGE STENT

5

BACKGROUND OF THE INVENTION

The present invention relates generally to stents. More specifically, improved stent designs that incorporate interlocking elements are described.

10

In recent years the use of stents in various endovascular and other medical procedures has become increasingly popular. Accordingly, a number of stent designs and insertion procedures have been proposed and used within the medical community. By way of example, U.S. Patent Nos. 5,593,412, 5,314,444, 5,135,536, 5,116,365 and 4,856,516, and European Patent Application No. EP 0 830,853 describe a few conventional stent designs. Generally, an expandable stent is placed over a balloon at the distal of an catheter and inserted into the vessel of interest. When the stent is properly positioned, the balloon is inflated thereby expanding the stent. The catheter is then withdrawn leaving the expanded stent in place within the vessel.

20

25

30

35

15

In many applications, the stent must travel along a tortuous path as it is inserted through the vessel. Therefore, one stent characteristic that is often desirable is that the stent be longitudinally flexible to permit it to bend easily as it is inserted. That is, it is desirable for the stent to readily bend along its length so that the stent can bend as necessary as it is inserted through a tortuous vessel. Other stent characteristics that are generally considered desirable include good radial strength after expansion and uniform expansion along the length of the stent. Although existing stents work well in many applications, there are always efforts to improve stent designs. Accordingly it is an objective of the present invention to provide new and useful improved stent designs.

SUMMARY OF THE INVENTION

To achieve the foregoing and other objects and in accordance with the purpose of the present invention, a variety of improved stent designs that utilize interlocking rings are disclosed. Each ring is arranged to have a plurality of expandable loops. In some embodiments, some of the loops on each ring are arranged to interlock with a portion of an adjacent ring. The mating structure on the adjacent ring may take the

form of loops or a dedicated interlocking structure. In other embodiments, separate interlocking members are used to interlock adjacent rings.

In some embodiments that incorporate interlocking members, some of the interlocking members include a retaining bar and a coupling member carried by the retaining bar. The coupling members are arranged to interlock with adjacent rings. The coupling members may be arranged to interlock with coupling members on the adjacent rings, or with loops within the adjacent rings. The coupling members may take the form of anchors, hoops, sockets, balls and a wide variety of other structures.

10

15

20

5

In various other embodiments, each ring includes a pair of wires each having a plurality of expandable loops with at least one linkage arranged to couple the wires. At least some of the loops on each ring are arranged to interlock with a portion of an adjacent ring when the stent is in an unexpanded condition. In some implementations, the wires within a ring are substantially mirror images of one another and the linkages couple apexes of adjacent loops in their associated wires. In others the first and second wires have different geometries and are arranged such that apex portions of their adjacent loops are complementary.

In still other embodiments, the rings are configured such that adjacent rings have different geometries and are arranged so that apex portions of loops on adjacent rings are complementary. In some cases, the adjacent rings may be coupled together.

25 BRIEF DESCRIPTION OF THE DRAWINGS

The invention, together with further objects and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying drawings in which:

FIGURE 1 is a pattern diagram of a linkage stent in accordance with one embodiment of the present invention.

FIGURE 2 is a pattern diagram of a linkage stent in accordance with a second embodiment of the present invention.

35

FIGURE 3 is a pattern diagram of a linkage stent in accordance with a third embodiment of the present invention.

FIGURE 4 is a pattern diagram of a linkage stent in accordance with a forth embodiment of the present invention.

FIGURE 5 is a pattern diagram of a linkage stent in accordance with a fifth embodiment of the present invention.

FIGURE 6 is a pattern diagram of a linkage stent in accordance with a sixth embodiment of the present invention.

FIGURE 7 is a pattern diagram of a linkage stent in accordance with a seventh embodiment of the present invention.

FIGURE 8 is a pattern diagram of a linkage stent in accordance with an eighth embodiment of the present invention.

15

20

25

30

35

10

DETAILED DESCRIPTION OF THE INVENTION

A few embodiments of the invention will now be described with reference to the drawings. Figures 1-8 illustrate a few specific stent patterns in accordance with various aspects of the invention. The described stents include a plurality of rings that are arranged to interlock with one another at least when the stent in crimped for insertion into a vessel such as an artery. A variety of interlocking mechanism are described. In some embodiments, loops formed within adjacent rings are arranged to interlock, while in other embodiments dedicated interlock mechanisms are used. In still other embodiments a combination of the two approaches are used. The described stent designs have very good longitudinal flexibility and are radially strong which make them ideal for a number of applications. Several of the embodiments also have a relatively large surface areas that are relatively evenly distributed in the expanded position which make them good for the delivery of radiation in applications where radiation is desired.

As will be appreciated by those skilled in the art, the stent patterns are shown in a planer layout. To form the stent, the top portion of the stent pattern is attached to the bottom portion of the stent pattern, thereby forming a tubular structure. To assist in the visualization of the patterns, in many of the drawings, specific rings are shown with cross-hatching. This is not intended to suggest that adjacent rings would typically be formed from different materials, rather the cross-hatching is utilized to make it easier to visualize the ring patterns.

Referring initially to Figure 1, a stent 18 in accordance with the first described embodiment includes a plurality of interlocking rings 20 and a pair of end rings 24. As best seen at the right side of Figure 1 wherein the geometry of a single interlocking ring 20 is shown cross hatched, the interlocking rings 20 each have a pair of matching wires 25, 26 that are each arranged in a serpentine manner to form a plurality of inner and outer loops 28 and 29 and are essentially mirror images of one another. The wires within the same ring are coupled by connecting bars 27 which couple the apexes of adjacent inner loops 28.

10

15

20

25

30

35

As best seen in Figure 1, adjacent interlocking rings 20 are vertically staggered from one another and positioned such that the inner loops 28 of a first wire 25 on a first ring 20, are arranged to receive the outer loops 29 of a second wire 26 of an adjacent ring 20, and vice versa. The inner and outer loops are sized such that the maximum diameter d₁ of the outer loops is less then the diameter of constrictions d₂ in the inner loops. With this arrangement, adjacent rings are effectively interlocked by the mating engagement of the inner and outer loops of adjacent ring wires.

The actual dimensions of various ring, wire, connecting bar and loops may be widely varied depending upon the needs of a particular system. The number of interlocking rings used in a particular stent will depend in large part upon the desired overall stent length, as well as the length of connecting bars 27 and the length L_1 of the outer loops 29. Similarly, the number of loops in each ring utilized in a particular stent will depend in large part upon the desired overall stent diameter, as well as the distance between adjoining loops. By way of example, in one specific implementation, each wire 25, 26 in each interlocking ring 20 is formed into four loops having a longitudinal width of 0.1 mm, an inner loop centerline radius of .275 mm, an outer loop centerline radius of .475 mm, a gap between adjacent loops of 0.1 mm and a ring pitch of 3.75 mm. Since each ring has two wires, the wire pitch averages about 1.9 mm.

In the embodiment shown in Figure 1, the stent 18 includes a pair of end rings 24 located on opposite ends of the stent. Each end ring is a single wire serpentine ring that is arranged to mate with one side of an adjacent interlocking ring 20. The inner and outer loops of the end rings match the sizes of the inner and outer loops of the interlocking rings to provide good interlocking between the end rings and their adjacent interlocking rings. Thus, it should be appreciated that in the embodiment shown, the diameters of the inner and outer loops of the end rings are not the same.

In alternative embodiments the end rings can be eliminated. The illustrated design can be varied in a number of ways. In the embodiment shown, the inner and outer loops of the interlocking rings have different diameters, but the interlocking rings have the same dimensions from ring to ring. The only difference is that adjacent rings are offset from one another by half a loop such that their respective loops interlock. However, there is no requirement that the interlocking rings have the same geometry as one another. Rather, the size of the various loops can be varied somewhat as long as they remain complementary with their neighbors. Similarly, each loop of each ring is shown to interlock with a loop on an adjacent ring. However, true interlocking could be provided on only some of the loops. Further, the connecting bars are illustrated as occurring between each of the inner loop apexes of adjacent wires within a ring. However, it would be possible to utilize fewer connecting bars as well.

The described linkage stent structure is extremely flexible longitudinally and is radially strong. When the stent is expanded (not shown), the loops stretch out in a manner that gives a relatively uniform distribution of the surface area of the stent which is desirable in many situations. It is noted that in the embodiment shown in Figure 1, the rings are interlocked before the stent is expanded, but after expansions there is no physical connection or other coupling between the rings. Thus, there are a series of independent adjacent rings. In most applications, the body vessels (such as arteries) that the stents are placed in are somewhat resilient and therefore the vessel will naturally hold the expanded rings in place and prevent the rings from dislodging or slipping after the stent has been placed.

25

30

35

5

10

15

20

In some circumstances, it may be desirable to provide a mechanism for coupling the various rings together even in the expanded state. Referring next to Figure 2, a second embodiment will be described which physically couples its adjacent interlocking rings 30. The interlocking rings 30 in this embodiment are formed substantially the same way as the interlocking rings 20 described above with respect to Figure 1. The only difference is that adjacent rings are coupled together by connectors 32 that couple sidewall portions 33 of adjacent loops 37, 39. The connectors 32 are arranged to couple sidewall portions of adjacent loops so that the longitudinal stability of the stent is not significantly compromised during expansion of the stent. It should be appreciated that if the inter-ring connectors 32 were to connect adjacent loop apexes, the stent would significantly contract longitudinally during expansion. By connecting the sidewalls of the loops, the amount of longitudinal contraction that is likely to occur during expansion is minimized. In the

embodiment shown, each interlocking ring 30 is coupled to its neighbor by a single inter-ring connector 32. In other embodiments, multiple inter-ring connectors may be utilized between each pair of adjacent rings. The potential disadvantages of adding multiple inter-ring connectors between each adjacent pair of rings is that it would decrease the longitudinal flexibility of the stent as well as increase the likelihood of longitudinal contraction of the stent during expansion. In the embodiment shown, the inter-ring connectors 32 are staggered circumferentially about the stent so that they do not lie in a line. This also helps the longitudinal flexibility of the stent. However, in alternative embodiments the circumferential placement of the connector bars could be widely varied.

The embodiment illustrated in Figure 2 has the advantage of affirmatively coupling adjacent rings while maintaining good radial strength and longitudinal flexibility. In some implementations, the affirmative coupling of adjacent rings may be desirable to provide additional ring stability, particularly in the expanded state.

10

15

20

25

30

35

The embodiments illustrated in Figures 1 and 2 have a good density of wires, especially when compared to conventional stent designs. When the stent is expanded, the pattern is relatively uniform in terms of not having large holes in it. Relatively higher wire densities and relatively uniform wire distribution in the expanded state are a couple of characteristics that are often desirable in stent design. Higher wire densities are often desirable to improve the mechanical ability of the stent to hold material, such as artherioslorotic plaque, in place within an artery. Another application where higher wire densities may be desirable is when the stent is used to deliver radiation. In these applications, the higher wire densities, in general, facilitate more uniform delivery of the radiation.

Referring next to Figure 3, another stent design that facilitates even higher wire densities will be described. In the embodiment show, the stent 40 takes the form of a series of alternating uniform rings 41 and interlocking rings 42 which have different shapes. The first set of rings 41 have a uniform serpentine shape having a plurality of back to back uniform loops 44. A second set of rings 42 are arranged to have exaggerated interlocking loop segments 45 that are adapted to be received by the uniform loops 44 in their adjacent rings 41. The shape of the loops 45 in the interlocking rings 42 are extended so that they alternate back and forth between the inner portions of the uniform loops 44 a pair of adjacent uniform rings 41. As can be seen in Figure 3, the uniform rings 41 do not overlap with one another in this embodiment, although the interlocking rings 42 do overlap in the unexpanded state.

It should be appreciated that one advantage of the described structure is that even higher wire densities can be obtained using this design. By way of example, using standard loop sizes, center to center distances between adjacent wires on the order of one millimeter are readily available using current technology.

Even more so then the embodiment described with respect to Figure 1, the design of Figure 3 provides a large number of independent (in this case single wire) rings which typically will not be coupled after the stent has been expanded. Therefore, in some embodiments it may be desirable to add connecting bars (not shown) at strategic locations between adjacent pairs of rings 41 and 42. By way of example, each of the uniform rings 41 could be physically coupled to an adjacent associated one of the interlocking rings 42. In still other embodiments it may be desirable to utilize offset connecting bars to couple more then a pair of adjacent rings.

15

20

25

30

35

10

5

Referring next to Figure 4, yet another embodiment of the invention will be described. In this embodiment the stent 50 has a plurality of interlocking rings 52 and an end ring 51 each having a generally uniform serpentine configuration. A retaining bar 54 is coupled to the apex of each loop 53 on one side of each interlocking ring 52 (the left side in the orientation illustrated in Figure 4). Each retaining bar 54 includes an anchor 55 at its distal tip. The width of the retaining bars 54 are sized to pass through the narrow gap 57 formed between adjacent loops in an adjacent ring. At the same time, the diameter of the anchors 55 are sized to be larger then the narrow gaps 57 but still fit within the adjacent loop to form an anchor that interlocks adjacent rings when the stent is in the unexpanded or crimped position. In the illustrated embodiment, the end ring 51 does not have the described retaining bars.

As with the previously described embodiments, the dimensions of the various components of stent 50 can be widely varied. For example, the loop size and retaining bar lengths can be varied to increase or decrease the distance between adjacent rings. By way of example, in one embodiment, each interlocking ring 52 is formed from a flat wire having a total length of 5 mm, that is formed into five loops 53 having a longitudinal width of 0.1 mm, an inter-loop gap 57 of 0.25 mm and a maximum inner loop diameter 58 of 0.625 mm. In such an embodiment, the retaining bars 54 may have a length in the range of 0.5 mm to 1.0 mm and the anchors 55 may have an outer diameter of 0.4 mm. One advantage of the described structure is that adjacent rings may be placed very close together. By way of example in the described embodiment

5

10

15

20

25

30

35

ring pitches (i.e. the distance between adjacent rings) on the order of 1.5 mm are readily obtainable.

The geometry and dimensions of the described anchors 55 may be widely varied. In embodiments that are intended to deliver radiation, the anchors are preferably not solid elements since solid elements are likely to form "hot" spots which deliver too much radiation to a small area. By way of example, in the illustrated embodiment, the anchors are formed as hoops as opposed to solid elements. Such an arrangement reduces the amount of metal in a concentrated region in the expanded position which is generally desirable in embodiments which are intended to deliver radiation. Although a generally hoop-shaped anchor is illustrated, other anchor geometries, as for example ovals, teardrops and ellipses may be readily used.

When the stents illustrated in Figure 4 are expanded, it has been observed that there is some twisting that causes the retaining bars 54 to extend outward from the generally cylindrical tube formed by the expanded rings 52. Thus, the anchors 55 extend at least partially outward. The amount of protrusion of the anchors depends on a number of factors including, most notably, the length of the retaining bars and width of the wires used to form the interlocking rings. In practice, the amount of anchor protrusion can be controlled somewhat by varying the various design parameters. In some implementations, this "out-of-plane" extension of the anchors 55 can be used to effectively form "hooks" that protrude into vessel walls to help anchor the stent. When desirable, the geometry of the anchors can be varied to form barbed structures that further enhance the anchoring ability of the anchors 55.

Although the embodiments described with reference to Figure 4 have several applications, in many other applications it is undesirable to have significant out-of-plane extension of the anchors. Further, it should be appreciated that in the expanded position, the adjacent rings do not interlock, which is considered undesirable in some implementations. These drawbacks are addressed in the stent 60 illustrated in Figure 5.

Referring next to Figure 5, stent 60 utilizes ball and socket type structures to interlock adjacent rings. More specifically, in the embodiment shown, the stent includes a male end ring 61, a plurality of interlocking rings 62 and a female end ring 63. Each of the rings has a generally uniform serpentine configuration and a plurality of coupling members that are arranged to mate with coupling members on an adjacent

ring to form socket type structures that interlock adjacent rings. A male coupling member 65 is coupled to the apex of each loop 66 on one side of each interlocking ring 62 (the right side in the orientation illustrated in Figure 5). A female coupling member or socket 68 is coupled to the apex of each loop 69 on the other side of each interlocking ring 62 (the left side in the orientation illustrated in Figure 5). In the illustrated embodiment, the end rings 61 and 63 each have just one set of coupling members. In this embodiment, the loops of adjacent rings do not interlock directly with one another or with a coupling element from an adjacent ring as described in the previous embodiments. Rather, the coupling members 65, 68 effectively form anchors which couple adjacent rings. One advantage of the described structure is that adjacent rings remain interlocked even after the stent has been expanded.

5

10

15

20

25

30

35

In the illustrated embodiment, each coupling member 65, 68 is carried by a short retaining bar 70, 71. The use of short retaining bars tends to reduce the out-of-plane bending of the coupling embers as compared to the embodiment described above with respect to Figure 4. The male coupling members 65 take the form of hoops, while the female coupling members 68 take the form of sockets that engulf the hoops. As described above with reference to Figure 4, the primary reason for using hoops 65 in the illustrated embodiment is to facilitate the delivery of radiation without forming hot spots. In embodiments where radiation is not to be delivered, there would be no need to form the male members as hoops. Indeed the geometry of the coupling members 65, 68 may be widely varied so long as they mate appropriately.

The stent design illustrated in Figure 5 has good radial strength and is longitudinally quite flexible. As described above, one common requirement for stents is that they be longitudinally flexible to permit their delivery through and implantation within tortuous vessels within a body. While the illustrated embodiment generally has good longitudinal flexibility, it should be appreciated that at some point of bending, one or more of the sockets 68 will bottom out against the retaining bar 69 that carries its associated hoop 65. Thus, the described structure is extremely flexible until the stent is bend to the point where some of the sockets 68 press against their associated retaining bars 69.

In some stent that have been tested, twisting of the type described with respect to Figure 4 occurs to some extent. That is, the loops may experience some twisting that causes the hoops 65 and sockets 68 to extend outward from the generally cylindrical tube formed by the expanded rings 62. As before, the amount of

protrusion of the anchors depends on a number of factors including, the length of the retaining bars and width of the wires used to form the interlocking rings. In general, the retaining bars are shorter and thus the out of plane movement tends to be reduced, which in many applications may be desirable.

5

Referring next to Figure 6, yet another socket based interlocking stent 72 will be described. This embodiment is quite similar to the hoop and socket interlocking arrangement described above with respect to Figure 5. However, in this case, the hoops are replaced by balls 75. In the embodiment shown, the balls 75 are substantially spherical, although their geometry can be widely varied. The point in this embodiment is that the balls 75 have more depth then the hoops 65. Therefore, it is less likely that the male and female coupling members will disengage in the event that there is out of plane movement of the retaining bars 70, 71.

15

10

In some implementations, it may be desirable to insure that adjacent rings in a stent are positively coupled even after expansion of the stent. Referring next to Figure 7, yet another stent design will be described. This embodiment is very similar to the embodiments of Figures 5 and 6, except that the male/female interlocking arrangement is replaced by interlocking hoops 85 that are carried retaining bars coupled at the apexes of adjacent rings.

20

25

In the embodiments shown in Figures 5-7, each adjacent pair of loop apexes carries an appropriate interlocking member. However, in alternative embodiments, it may be desirable to provide fewer interlocking mechanisms between adjacent rings. By way of example, the interlocking mechanism on adjacent ring pairs may be staggered circumferentially about the stent so that they do not lie in a line. Such an arrangement would helps the longitudinal flexibility of the stent. In still other alternative embodiments the number of interlocking members provided on each ring, as well as their circumferential placement can be widely varied. Also, a number of the design parameters including loop and coupling member sizes can be widely varied to meet the needs of a particular design. Further, the retaining bars 70, 71 that carry the coupling members may be elongated, shortened or even eliminated as desired to appropriately size the stent.

35

30

Referring next to Figure 8, yet another interlocking stent 90 will be described. This embodiment is quite similar to the hoop/ball and socket interlocking arrangement described above with respect to Figure 5 and 6. However, in this case, the rings 92 have the same orientation such that loops 93 from adjacent rings 92

match. The retaining bars 95, 96 are sized such that the interlocking members 97, 98 nest within an associated loop 93. That is, a retaining bar that extends from an apex of a loop on one ring extends into the matching loop on an adjacent ring. The interlocking members 97, 98 are thus positioned within the matching loop. In the embodiment shown, the interlocking members take the form of balls and sockets as described above with respect to Figure 6. However, it should be appreciated that the above described hoop and sockets or interlocking hoops arrangements, as well as other suitable interlocking configurations may readily be used as well. As with the previously described embodiments, the number of interlocking members provided on each ring, as well as their circumferential placement can be widely varied. Also, a number of the design parameters including loop and coupling member sizes can be widely varied to meet the needs of a particular design. Further, the retaining bars that carry the coupling members may be elongated, shortened or even eliminated as desired to appropriately size the stent. The described geometry allows for closer rings spacing while providing good longitudinal flexibility. By way of example, ring pitches on the order of one millimeter are readily obtainable.

5

10

15

20

25

30

35

The described stents may be fabricated from any suitable biocompatible material such as stainless steel, gold, tantalum, nitinol or other materials well known to those skilled in the art. In the described stent designs, care has been taken to provide a relatively large stent surface area having a relatively even metal distributed in the expanded position, without creating large holes in the expanded position. Relatively higher wire densities and relatively uniform wire distribution in the expanded state are a couple of characteristics that are often desirable in stent design. Higher wire densities are often desirable to improve the mechanical ability of the stent to hold material, such as artherioslorotic plaque, in place within an artery. The higher wire densities also make the stents particularly well suited for the delivery of radiation in applications where radiation is desired. In applications where radiation is not to be delivered and/or the mechanical advantages are not deemed necessary, alternative interlocking ring configurations that create substantially larger openings may be utilized.

In this application, the mechanism used to implant the described stents have not been described. However, as will be appreciated by those skilled in the art the stents are readable inplantable using conventional delivery systems.

Although only a few embodiments of the present invention has been described, it should be understood that the present invention may be embodied in

5

10

15

20

25

30

many other specific forms without departing from the spirit or scope of the invention. Particularly, in several of the embodiments, interlocking mechanisms were provided on every loop of the stent rings. However, it should be appreciated that in many applications, the number of interlocking mechanisms between adjacent rings can be reduced to as few as one interlocking mechanism. This is particularly true in embodiments that retain interlocking between adjacent rings in the expanded state. In some stent designs it may be desirable to combine two or more of the described or analogous interlocking mechanisms to meet the design goals of a particular application. By way of example, it may be desirable to positively interlock some of the adjacent rings or sets of rings in a manner that remains interlocked in the expanded state, without requiring that all of the ring sets be interlocked in the expanded state. Further, some of the embodiments include one or more end rings that effectively cap a pattern used within the body of the stent design. In most situations, the end rings can be eliminated if desired. In other situations, appropriate end rings could be added.

Several specific stent dimensions have been given by way of example. However, as will be appreciated by those skilled in the art, the actual dimensions may vary widely based upon the application of the stent. One feature that should be apparent, however, is that the pitch of the described stents (i.e. the distance between adjacent rings/wires) are quite small when compared to conventional stent designs, with pitches in the range of 1 to 1.5 mm and smaller being readily attainable using conventional materials.

The inventions have been described primarily in the context of vascular stents, however, as will be appreciated be those skilled in the art, the described stents are suitable for placement in a wide variety of body vessels. Therefore, the present examples are to be considered as illustrative and not restrictive, and the invention is not to be limited to the details given herein, but may be modified within the scope of the appended claims.

IN THE CLAIMS:

5

15

1. An endovascular stent comprising a plurality of rings that are interlocked to form a tubular stent structure having an axial length, wherein the rings are interlocked in an axial direction of the stent.

- 2. An endovascular stent as recited in claim 1 wherein each ring includes a wire having a serpentine configuration that forms a plurality of loops.
- 10 3. A stent suitable for use in a body vessel, the stent comprising a plurality of interlocking rings, each ring including a wire having a plurality of expandable loops.
 - 4. A stent as recited in claim 3 wherein at least some of the plurality of loops on each ring are arranged to interlock with a portion of an adjacent ring.
 - 5. A stent as recited in claim 3 wherein at least some of the plurality of loops on a first one of the rings are arranged to interlock with at least some of the loops on a second one of the rings.
- 20 6. A stent as recited in claim 3 wherein a first set of the rings each include a second wire having a plurality of expandable loops, the second wire being coupled to the first wire by at least one linkage.
- 7. A stent as recited in claim 6 wherein the linkages couple apexes of adjacent loops in their associated first and second wires.
 - 8. A stent as recited in claim 5 further comprising at least one linkage arranged to couple a first sidebar portion of a first selected loop on the first ring to adjacent second sidebar portion of a second selected loops on the first wire.

30

35

- 9. A stent suitable for use in a body vessel, the stent comprising a plurality of interlocking rings, each ring having a plurality of expandable loops and at least one interlocking member arranged to interlock with an adjacent ring when the stent is in a non-expanded configuration.
- 10. A stent as recited in claim 9 wherein a first set of the interlocking members each include:

a retaining bar; and

20

an anchor carried by the retaining bar, wherein the anchor is arranged to interlock with an adjacent ring.

- 5 11. A stent as recited in claim 10 wherein a second set of the interlocking members each include a coupling member arranged to engage an anchor on an adjacent ring.
- 12. A stent as recited in claim 11 wherein the anchors are balls and the coupling members are sockets arranged to constrain the balls.
 - 13. A stent as recited in claim 11 wherein the anchors are hoops and the coupling members are sockets arranged to constrain the hoops.
- 15 14. A stent as recited in claim 10 wherein the anchor is arranged to interlock with an expandable loop of an adjacent ring.
 - 15. A stent as recited in claim 9 further comprising an end ring having a plurality of expandable loops, the end ring being interlocked to an adjacent ring by at least one of its expandable loops.
 - 16. A stent as recited in claim 9 wherein the interlocking members include hoops arranged to interlock with complimentary hoops on an adjacent ring.
- 25 17. A stent suitable for use in a body vessel, the stent comprising a plurality of interlocking rings each ring including:

first and second wires each having a plurality of expandable loops, wherein at least some of the plurality of loops on each ring are arranged to interlock with a portion of an adjacent ring;

- at least one linkage arranged to couple the first and second wires.
- 18. A stent as recited in claim 17 wherein at least some of the plurality of loops on a first one of the rings are arranged to interlock with at least some of the loops on a
 35 second one of the rings when the stent is in an unexpanded condition.
 - 19. A stent as recited in claim 18 wherein:

the linkages couple apexes of adjacent loops in their associated first and second wires; and

the first and second wires within each ring are substantially mirror images of one another.

5

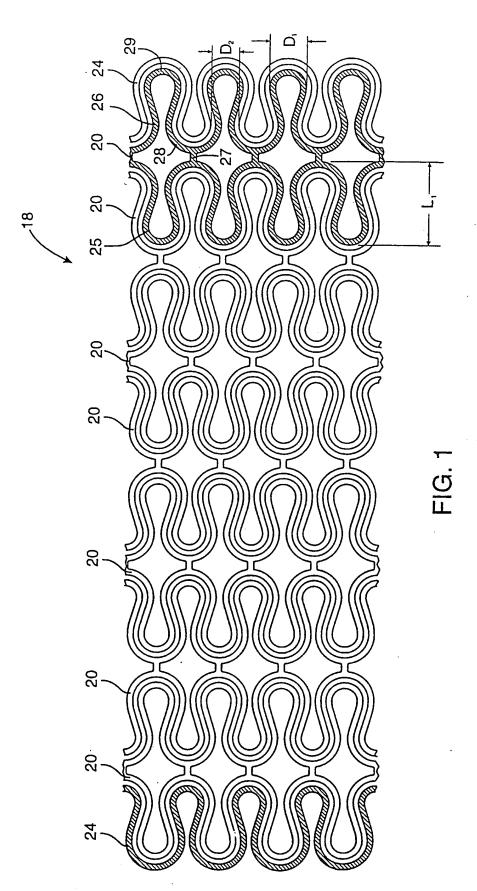
- 20. A stent as recited in claim 18 wherein the first and second wires have different geometries and are arranged such that apex portions of their adjacent loops are complementary.
- 10 21. A stent suitable for use in a body vessel, the stent comprising a plurality of interlocking rings, each ring including a wire having a plurality of expandable loops wherein at least some of the plurality of loops on each ring are arranged to interlock with at least some of the loops on an adjacent one of the rings.
- 15 22. A stent as recited in claim 17 wherein:

the rings include first and second end rings and a plurality of intermediate rings;

the rings are configured such that adjacent rings have different geometries and are arranged such that apex portions of loops on adjacent rings are complementary.

20

- 23. A stent as recited in claim 21 further comprising at least one linkage arranged to couple a first selected pair of adjacent rings.
- 25 24. An endovascular stent comprising a plurality of interlocking rings.



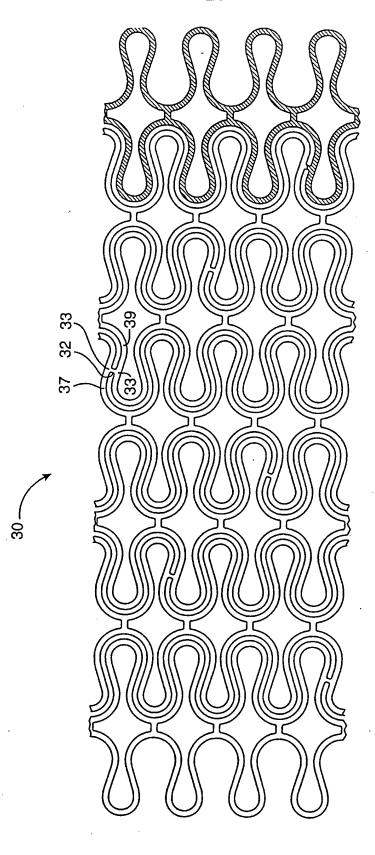
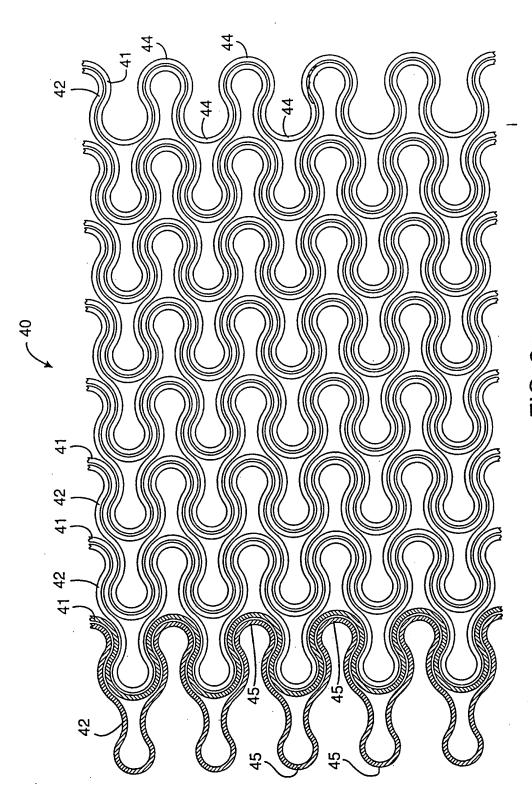
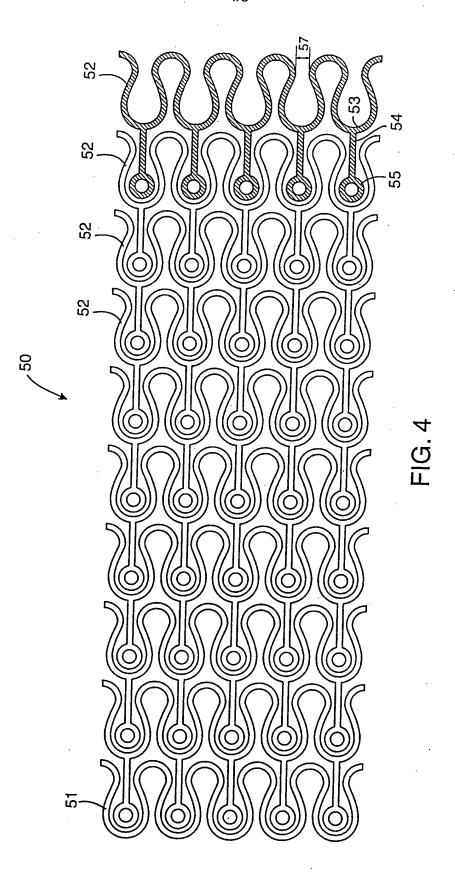
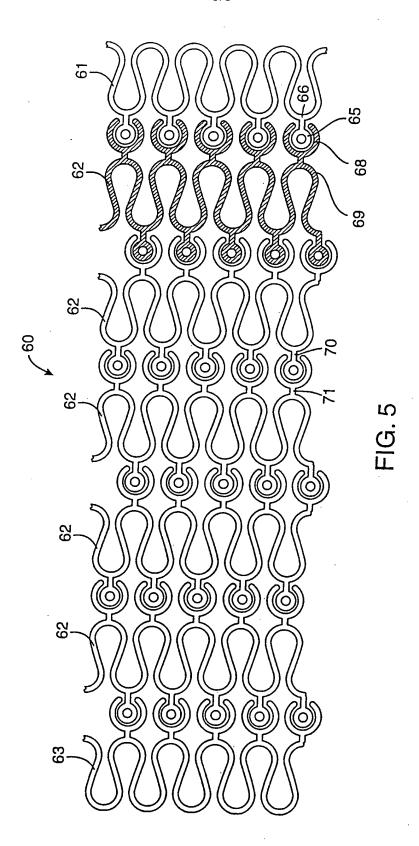


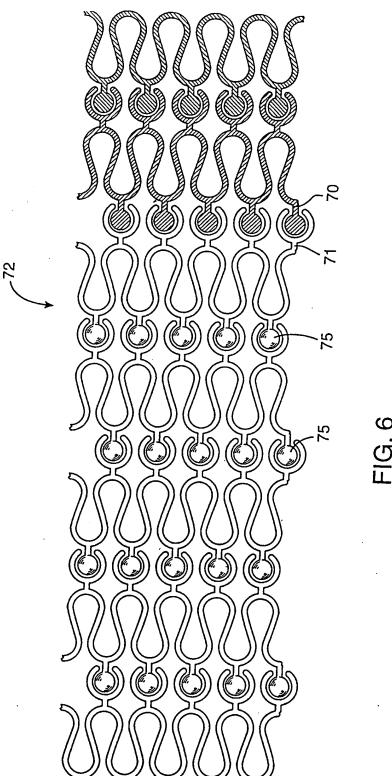
FIG. 2

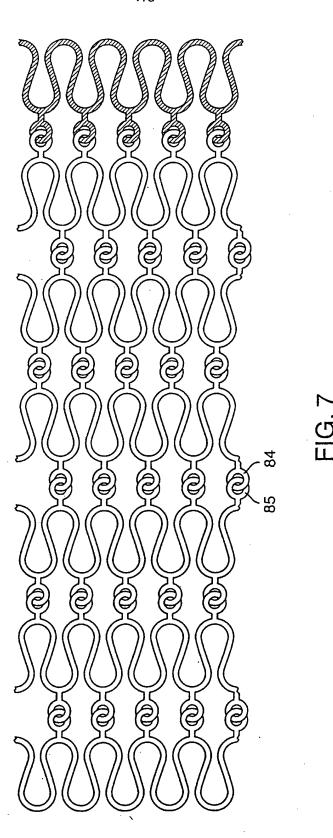












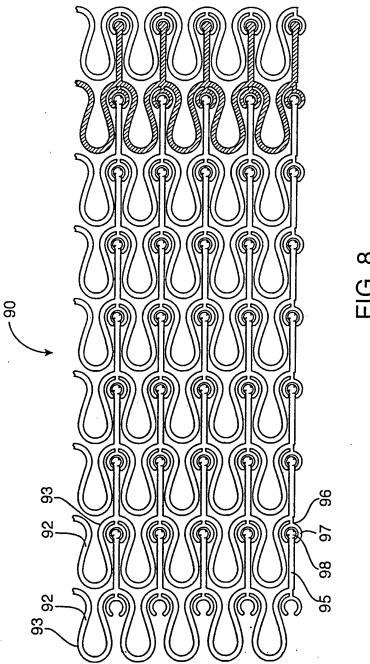


FIG. 8





onal Application No

PCT/US 99/21106 A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61F2/06 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61F Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Category : Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. X 1-9,21,DE 196 30 469 A (BETZLER MICHAEL PROF DR MED) 29 January 1998 (1998-01-29) 24 column 5, line 16 -column 6, line 11; figures 17-19 US 5 741 327 A (FRANTZEN JOHN J) 1-7,9-24 21 April 1998 (1998-04-21) column 8, line 18 -column 11, line 38; figures 7-19 X WO 97 12562 A (MEDTRONIC INC) 1.9-12. 10 April 1997 (1997-04-10) page 36, line 11 -page 38, line 22; figures 10-14 Α 13,16 -/--Further documents are tisted in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) Involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combined with one or more other such documents, such combination being obvious to a person skilled in the art. "O" document referring to an oral disclosure, use, exhibition or document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report

12 January 2000 Name and mailing address of the ISA

Authorized officer

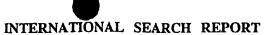
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 epo nl. Fax: (+31-70) 340-3016

Neumann, E

19/01/2000

Form PCT/ISA/210 (second sheet) (July 1992)

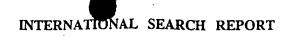
2





PCT/US 99/21106

| C.(Continua | ition) DOCUMENTS CONSIDERED TO BE RELEVANT | |
|-------------|--|----------------------|
| Category ' | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No |
| Х | WO 97 49353 A (MEDTRONIC INC) 31 December 1997 (1997-12-31) figure 5 | 1-3,24 |
| X | WO 98 27894 A (PROGRAFT MEDICAL INC) 2 July 1998 (1998-07-02) page 14, line 22 -page 17, line 1; figure 5 | 1,2,24 |
| Ρ,Χ | DE 197 28 337 A (INST MIKROTECHNIK MAINZ GMBH) 7 January 1999 (1999-01-07) the whole document | 1,9-16, 24 |
| · | | |
| | | |
| | | |
| į | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| · | | |
| | | |



.iformation on patent family members

•

Inter anal Application No PCT/US 99/21106

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|---|---|------------------|---|--|
| DE 19630469 | Α | 29-01-1998 | NONE | |
| US 5741327 | Α | 21-04-1998 | NONE | |
| WO 9712562 | A | 10-04-1997 | US 5824037 A EP 0855883 A JP 11512635 T US 5824040 A US 5824042 A | 05-08-1998 02-11-1998 20-10-1998 — |
| WO 9749353 | Α | 31-12-1997 | EP 0928169 A | 14-07-1999 |
| WO 9827894 | Α | 02-07-1998 | AU 5458298 A | 17-07-1998 |
| DE 19728337 | Α | 07-01-1999 | WO 9901087 A | 14-01-1999 |